RECEIVED AT DRUG SAFETY SURVEILLANCE
19-FEB-1998-0604

McNEIL CONSUMI
FORT WASH

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Individual Safety Report
3032479-4-00

5/93

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
Case 228 In confidence	40 yrs or Date of birth:	(X)female ( )male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

(X) death 1/16/96 (mo/day/yr)
( ) life-threatening
(X) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
1/96	02/06/98

5. Describe event or problem

Case # 228 received from the [redacted] 1996 case fatality data.
See attached case report form provided by [redacted]

FEB 1 2 1998

6. Relevant tests/laboratory data, including dates

See attached case report form provided by [redacted]

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

See attached case report form provided by [redacted]

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 acetaminophen/butalbital/caffeine
#2

2. Dose, frequency & route used
#1 unknown dose, po
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 1/96
#2

4. Diagnosis for use (indication)
#1 unknown
#2

5. Event abated after use stopped or dose reduced
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)
#1 Unknown
#2

7. Exp. date (if known)
#1 Unknown
#2

8. Event reappeared after reintroduction
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)
See attached case report form provided by [redacted]

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number
215-233-7820

3. Report source (check all that apply)
( ) foreign
( ) study
(X) literature
( ) consumer
(X) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr)
01/30/98

5.
(A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)
( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) initial ( ) follow-up #

8. Adverse event term(s)
SOMNOLENCE STUPOR
HYPERKALEMIA CREATININE INC
LIVER FUNC ABNO ACIDOSIS
DEATH

9. Mfr. report number
0929449A

E. Initial reporter

1. Name, address & phone #
[redacted] MD
[redacted] Centers
Suite [redacted] Avenue
[redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	physician	( ) Yes ( ) No (X) Unk

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

[redacted] TESS FATALITY: 1996 [redacted]

Case Number: 228

Age:	40 yrs
Substances:	Acetaminophen/butalbital/caffeine
Chronicity:	Acute on chronic
Route:	Ingestion
Reason:	Int Unknown
Pre-Hospital Arrest?	No

On January 14, 1996 at 1222 a doctor contacted the Poison Control Center about a 40 year old female who had been sleeping for 2 days prior to admission according to her mother. The patient was discharged from a correctional institution immediately prior to that and went to the dentist for oral surgery. She allegedly ingested unknown amounts of Vicodan, Tylenol #3, and carisprodol(Soma) at that time.

In the emergency department she was described as unresponsive to painful stimuli. Vital signs were unavailable. Initial laboratory tests were sodium 141 (135-145 mEq/L), potassium 6* (3.5-5 mEq/L), chloride 101 (95-106 mEq/L), CO_2 12* (24-30 mEq/L), BUN 14 (5-25 mg/dl), creatinine 4* (0.5-1.5 mg/dl), AST 2830*(0-4. IU/L), ALT 3010* (0-45 IU/L), LDH 2307* (50-170 IU/L), CPK 1224* (0-255 IU/L), pH 7.17* (7.35-7.45 mmHg), pO_2 51* (65-77mmHg), pCO_2 29* 34-46 mmHg), O_2 Sat 100% (90-100%).

Toxicology analysis of serum revealed acetaminophen 4.9 ug/ml, aspirin 0 mg/dl, ethanol 3 mg/dl, butalbital 72 ug/ml. Toxic screen of urine was positive for benzodiazepines, barbiturates, and opioids.

The patient was intubated and put on assisted ventilation after receiving the following: sodium bicarbonate, lidocaine, dopamine, norepinephrine and isoproterenol infusions, dextrose 50%, thiamine and naloxone 10 mg(without response). The patient rapidly deteriorated over the next day and expired on 1/16/96.

Autopsy results are pending.